AMENDMENT UNDER 37 C.F.R. § 1.116 Attorney Docket No.: Q80638

U.S. Application No.: 10/807,369

REMARKS

Status of the Application

Claims 1 and 3-16 are all the claims pending in the application. Claims 8-9 and 11-16 are withdrawn from consideration as being directed toward an invention that is distinct from the invention originally claimed. Claims 1, 3-7 and 10 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claims 1, 3-7 and 10 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 3, 5-6 and 10, as best understood, stand rejected under 35 U.S.C. § 102(b) as being anticipated by Saito et al. (EP 0 562 425 A1), hereinafter "Saito". Claims 1, 3, 5-6 and 10, as best understood, stand rejected under 35 U.S.C. § 102(e) as being anticipated by Hiramatsu et al. (US Publication 2004/0086429), hereinafter "Hiramatsu". Claims 4 and 7, as best understood, stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Saito (EP 0 562 425 A1) or Hiramatsu (US Publication 2004/0086429), in view of Lappe (US Patent 5,902,982).

By this Amendment, Applicant hereby amends claims 1, 5 and 10. Applicant respectfully submits that these amendments should be entered and considered as they adopt a change suggested and contemplated by the Examiner.

Claim Rejections - 35 U.S.C. § 112

Claims 1, 3-7 and 10 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was

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not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 1, 3-7 and 10 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Based on the Examiner's rejection, Applicant hereby amending claims 1 and 5 in order to obviate the rejection. Applicant points the Examiner to page 29, line 8-page 32, line 2 for support.

With regard to claim 10, Applicant amends the claim in order to obviate the rejection. Further, Applicant notes that the reagent type/reagent lot information noted at the top of page 30 of the specification corresponds to the recited plurality of analytical information pieces. The term "analytical information" is a comprehensive expression, which includes a plurality of pieces of information (i.e., analytical information pieces). As is recited in Claim 1, the analytical information corresponds to the dry element information, which is intended to mean that the analytical information is determined based on the dry element information. In this respect, the analytical information is not exactly identical with the dry element information, but they closely correlate one another. Since the analytical information pieces make up the analytical information, the analytical information pieces also correspond to the dry element information in the above-mentioned sense. The dry element information includes the reagent type information, the reagent lot information and the like.

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Claim Rejections - 35 U.S.C. § 102

Claims 1, 3, 5-6 and 10, as best understood, are rejected under 35 U.S.C. § 102(b) as being anticipated by Saito et al. (EP 0 562 425 A1), hereinafter "Saito".

Claim 1 recites, in part, "the analysis apparatus further comprising a control system comprising an error handling processing function which calculates the analysis result based on pre-obtained analytical information corresponding to the reagent lot and adds a caution mark to the analysis result to attract attention, when the reagent lot information is not read out successfully." The Examiner alleges that Saito discloses all of the elements of claim 1. Applicant respectfully disagrees.

With regard to claim 1, on page 7 of the Office Action, the Examiner indicates that the addition of a caution mark is not attributed patentable weight, as it is a method step in the context of a claim addressed to physical hardware. However, in the Response to Arguments, the Examiner alleges that even if the addition of a caution mark is attributed patentable weight, the alarm sound in Saito corresponds to the caution mark recited in claim 1. Specifically, the Examiner argues that the alarm generates a sound to attract attention when a different reagent lot information is used (i.e., reagent lot information is not read out successfully).

Applicant submits that the amendments to claims 1 and 5 should give the recited elements patentable weight, as they are recited as part of a function of a control system.

The alarm in Saito is produced upon the occasion that the "variable information" for an analysis slide is different than the number previously read in and stored, the "variable information" including correction of fluctuation of measured or calculated values and a

correction coefficient of the standard curve predetermined for each lot. Production dates and usable periods may also be included in the variable information. It appears that the "variable information" may correspond to the reagent lot information disclosed in claim 1. Saito also indicates that "fixed information" is included with each analysis slide, the "fixed information" including code of a predetermined analyte, name of the analyte, amount of liquid, etc.

However, Saito fails to indicate that a caution mark is added to analysis result if the "variable information" is not read out successfully. Rather, Saito simply indicates that if the "variable information" read out is different from the "variable information" previously read in, an alarm sounds. This is not analogous to adding a caution mark to an analysis result as alleged by the Examiner. Rather, the alarm only sounds to prevent an inappropriate correction from being performed on the analysis result. Thus, if the analysis result obtained in Saito is recorded after the alarm is sounded, no further caution mark to attract attention would be saved with the analysis result. Therefore, claim 1 is patentable over the applied art.

Further, the object of Saito et al, is to prevent erroneous correction processing. In Saito et al., an alarm is output during processing so as to draw attention of an operator to prevent erroneous processing. In contrast, claim 1 of the present application, recites that a "caution mark" is attached to the analysis result so that a user can identify whether a readout error has occurred in the process of obtaining the analytical result even after the processing has ended. Therefore, the "caution mark", recited in claim 1, is completely different from the "alarm". Further, in an exemplary embodiment of the apparatus recited in claim 1, even if an error occurs during readout of reagent lot information, measurement does not stop. Since the measurement continues, re-measurement operation is not needed, thereby enabling efficient analysis

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processing. Also, since the "caution mark" is attached to the analytical result, it is possible to identify whether a readout error has occurred. Hence, the reliability of the analysis result is improved (please refer to the descriptions at page 7, lines 4 through 21 in the specification of the present application).

Claim 5 recites elements analogous to claim 1 and is patentable for reasons analogous thereto. Claims 3, 6 and 10 are patentable at least by virtue of their dependency from claim 1.

Claim 10 should further be patentable for reasons independent from is dependency. Specifically, claim 10 recites, "calculating the analysis result using the proper analytical information piece." Saito does not disclose that during error handling process, calculating the analysis result using a proper analytical information piece. Rather, once the alarm in Saito sounds, no further calculations are performed. Thus claim 10 is allowable over the applied art.

Claims 1, 3, 5-6 and 10, as best understood, are rejected under 35 U.S.C. § 102(e) as being anticipated by Hiramatsu et al. (US Publication 2004/0086429), hereinafter "Hiramatsu".

Claim 1 recites, in part, "the analysis apparatus further comprising a control system comprising an error handling processing function which calculates the analysis result based on pre-obtained analytical information corresponding to the reagent lot and adds a caution mark to the analysis result to attract attention, when the reagent lot information is not read out successfully." The Examiner alleges that Hiramatsu discloses all of the aspects of claim 1. Applicant respectfully disagrees.

With regard to the caution mark recited in claim 1, the Examiner argues that the warning message disclosed in paragraph [0107] of Hiramatsu corresponds to this feature. However, as

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when measurement analysis is not performed. See operations 473 and 480 in FIG. 7 of Hiramatsu. Thus, Hiramatsu fails to disclose not only that a caution mark is added to the analysis result, but fails to disclose that calculating the analysis result based on pre-obtained analytical information corresponding to the reagent lot when the reagent lot information is not read out successfully. Both of these elements require that an analysis result be obtained, while Hiramatsu indicates that when a warning message is produced, no analysis is performed. Thus, Hiramatsu cannot anticipate claim 1 and claim 1 is patentable over the applied art.

Further, in Hiramatsu et al., when an alert message is output, measurement is stopped. In contrast, claim 1 of the present application, recites that a "caution mark" is attached to the analysis result so that a user can identify whether a readout error has occurred in the process of obtaining the analytical result even after the processing has ended. Therefore, the "caution mark", recited in claim 1, is completely different from the "alarm". Further, in an exemplary embodiment of the apparatus recited in claim 1, even if an error occurs during readout of reagent lot information, measurement does not stop. Since the measurement continues, re-measurement operation is not needed, thereby enabling efficient analysis processing. Also, since the "caution mark" is attached to the analytical result, it is possible to identify whether a readout error has occurred. Hence, the reliability of the analysis result is improved (please refer to the descriptions at page 7, lines 4 through 21 in the specification of the present application).

Claim 5 recites elements analogous to claim 1 and are patentable for reasons analogous thereto. Claims 3, 6 and 10 are patentable at least by virtue of their dependency from claim 1.

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Claim 10 should further be patentable for reasons independent from is dependency. Specifically, claim 10 recites, "calculating the analysis result using the proper analytical information piece." Hiramatsu does not disclose that during error handling process, calculating the analysis result using a proper analytical information piece. Rather, once the alarm in Saito sounds, no further calculations are performed. Thus claim 10 is allowable over the applied art.

Claim Rejections - 35 U.S.C. § 103

Claims 4 and 7, as best understood, are rejected under 35 U.S.C. § 103(a) as being unpatentable over Saito (EP 0 562 425 A1) or Hiramatsu (US Publication 2004/0086429), in view of Lappe (US Patent 5,902,982).

Claims 4 and 7 depend from claims 1 and 5, respectively. Because Saito or Hiramatsu fail to disclose all of the aspects of claims 1 and 5, and because Lappe fails to cure the noted deficiencies in claims 1 and 5, claims 4 and 7 are patentable at least by virtue of their respective dependencies.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

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Respectfully submitted,

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